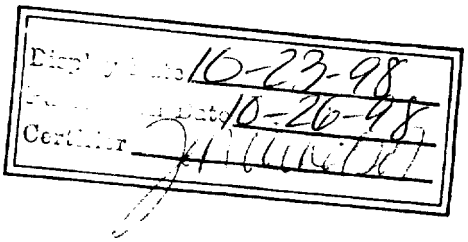
OMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0022]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by (*insert date 30 days after date of publication in the* **Federal Register).**

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, **5600** Fishers Lane, Rockville, MD 20857, 301-827-1223,

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control Number 0910-O171—Extension)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801 .421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting, fitting, and checking the performance of a hearing aid through distribution of a user instructional brochure. The user instructional brochure must also contain technical data about the device, instructions for its use, maintenance, and care, a warning statement, a notice about the medical evaluation requirement, and a statement if the hearing aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the user instructional brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the user instructional brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a user instructional brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the user instructional brochure to sellers for distribution to users and prospective users and provide a copy of the user instructional brochure to any health care professional, user, or prospective users who requests a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by

signing a written statement. Finally, the regulation requires that the dispenser retain, for 3 years, copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the user instructional brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.

The respondents to this collection of information are hearing aid manufacturers, distributors, dispensers, health professionals, or other for profit organizations.

In the **Federal Register** of June 30, 1998 (63 FR 35601), the agency requested comments on the proposed collection of information imposed on hearing aid manufacturers under §§ 801.420 and 801.421. FDA received one comment from an association representing hearing aid manufacturers. The comment stated that FDA underestimated the burden for preparing a user instructional brochure as required by § 801.420(c). The association stated that their member companies produced at least 18 different models of hearing aids and not the 5 assumed by FDA. The comment further stated that, because some models offer different features, their companies produced, on the average, 24 brochures for their 18 models. Finally, the comment stated that their member companies required not 40 hours, but at least 136 hours to produce a user instructional brochure.

FDA agrees in pat-t with the comment. FDA agrees that the number of models produced are more than the five originally estimated by FDA. FDA notes, however, that the estimates proposed by FDA are annual burdens. Not all 18 models and 6 variations cited by the comment are new

every year. Therefore, it is not necessary to prepare a new user instructional brochure for each of these every year. In addition, much of the information in the brochure can be transferred from one model brochure to the brochure for the successor model.

Based on premarket notification submissions, FDA estimates that approximately half of the models are significantly revised each year and others may be revised less significantly. FDA accepts the estimate of 136 hours for preparing a new brochure, but believes that an estimate of half that time or 68 hours is more appropriate for preparing a revised brochure.

The burden estimate for § 80 1,420(c) is calculated as follows: It is estimated that it will take 40 manufacturers 136 hours each to prepare 12 new brochures a year, which calculates to 65,280 hours. It is estimated that it will take those 40 manufacturers 68 hours to prepare 12 revised brochures a year, which calculates to 32,640 hours, Therefore, FDA estimates that it will take an average of 102 hours to prepare 24 brochures a year, which calculates to 97,920 hours.

FDA estimates the total burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801 .420(c)	40	24	960	102	97,920
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,900	5	49,700	0.17	8,449
Totals					586,369

[1] There are no capital costs or operating and maintenance costs associated with this collection of information,

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	162	1,600,000	0.25	400,000

[1]
[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the notice published in the **Federal Register** of June 30, 1998, § 801.421(a)(l) and (a)(2) were listed as imposing reporting burdens on the public. These provisions have been removed from the burden chart in this notice. Section 801.421(a)(1) imposes no reporting requirements on hearing aid dispensers, but appears to impose a burden upon patients, who must submit to the hearing aid dispenser an evaluation form (or a waiver under § 801.421(a)(2)) under this provision

prior to purchasing a hearing aid. This requirement is exempted from the definition of information because it consists of facts obtained from individuals in connection with direct treatment of a disorder (5 CFR 1320.3(h)(5)). Section 801 .421 (a)(2) requires dispensers to disclose to patients, prior to selling a hearing aid, that exercising the waiver of the evaluation form "is not in the patient's best health interest" (801 .421 (a)(2)(i)), This disclosure does not constitute a ' 'collection of information" because it is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)). Hence, the burden hours for these two provisions have been removed from the chart.

For the $801.42 1(b) estimate in Table 1 of this document, FDA assumes that 9,900 hearing aid dispensers will have 162 sales annually (1.6 million sales , the current number of annual hearing aid sales, divided by 9,900 dispensers). For all such sales, the dispenser must provide the prospective user a copy of the user instructional brochure and the opportunity to read and review the contents with him/her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

The $801,42 1(c) estimate in Table 1 of this document assumes that 9,900 dispensers (which includes 40 hearing aid manufacturers/distributors) will provide copies of the user instructional brochure to any health care professional, user, or prospective user who requests a copy in writing. It is estimated that five written requests for copies of the brochures will be received by each hearing aid manufacturer/distributor and dispenser annually. It is estimated that each request for a brochure will take .17 staff hours to complete. This effort consists of the hearing aid manufacturer/distributor or hearing aid dispenser locating the appropriate user instructional brochure for the specific model and mailing the brochure to the requester.

The $801.421 (d) recordkeeping estimate in Table 2 of this document assumes that 9,900 hearing aid dispensers will each retain 162 records. Each record documents the dispensing of a hearing aid to a hearing aid user. Each recordkeeping entry is estimated to require 0.25 staff hours,

Dated: October 14, 1998

October 14, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F